

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

INNOVATIVE THERAPIES, INC.,)
Plaintiff,)
v.) Civil Action No. 07-589-SLR
KINETIC CONCEPTS, INC., KCI LICENSING,)
INC., and KCI USA, INC.,)
Defendants.)

**OPENING BRIEF IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS COMPLAINT**

ASHBY & GEDDES
Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Tiffany Geyer Lydon (I.D. #3950)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
302-654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
tlydon@ashby-geddes.com

Of Counsel:

Don O. Burley
FINNEGAN, HENDERSON,
FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Avenue, NW
Washington, DC 20001
202-408-4000

Attorneys for Defendants

Erik R. Puknys
Jason M. Webster
FINNEGAN, HENDERSON,
FARABOW,
GARRETT & DUNNER, L.L.P.
3300 Hillview Avenue
Palo Alto, CA 94304
650-849-6600

R. Laurence Macon
AKIN GUMP STRAUSS HAUER
& FELD LLP
300 Convent Street, Suite 1500
San Antonio, TX 78205
210-281-7000

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184997.1

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I. PRELIMINARY STATEMENT

Innovative Therapies, Inc. (“ITI”) asserts that this Court has subject matter jurisdiction in the present declaratory-judgment action against Kinetic Concepts, Inc., KCI Licensing, Inc., and KCI USA (collectively “KCI”) based principally on statements made by two KCI employees during phone conversations they had with an ITI officer (and former KCI employee) named David Tumey. But these phone conversations—both of which were initiated by Mr. Tumey—were made under false pretenses for the sole purpose of manufacturing jurisdiction, and represent the height of procedural gamesmanship.

Mr. Tumey was a KCI employee from 1996 through 2004 and for the last five years of his career was KCI’s Director of Research and Development. After more than two years of not speaking with either of his former KCI colleagues, he contacted Michael Burke and Michael Girouard in September of this year under the pretext of making friendly conversation, even going so far as to tell Mr. Burke that he was seeking his “fatherly advice.” *See* discussion *infra* pages 4-6. However, neither Mr. Burke nor Mr. Girouard has any involvement in deciding whether KCI will sue anyone, and in any event their statements were neither fully nor fairly recounted in ITI’s complaint. In fact, both KCI employees made it quite clear that they could not say what KCI might do in response to Mr. Tumey’s claims that he was going to launch a competing product that neither they, nor anyone else at KCI, had ever seen. *See id.*

No dispute sufficient to establish declaratory-judgment jurisdiction exists between ITI and KCI, and this Court should dismiss ITI’s complaint as a result. Further, given ITI’s gamesmanship in attempting to manufacture a dispute between it and KCI where none existed, exercising jurisdiction here would be inconsistent with the purposes of the Declaratory Judgment Act. Accordingly, even if this Court were to conclude that jurisdiction exists, the Court should exercise its discretion under the Act to decline to hear ITI’s suit.

II. STATEMENT OF FACTS

A. The Parties and ITI's Product

ITI filed its complaint on September 25, 2007. As the complaint notes, KCI has manufactured and sold a variety of negative pressure wound therapy devices. Complaint ¶ 9. It is also correct that KCI's devices are covered by a variety of patents. *Id.*

According to the complaint, ITI was founded in 2006 by "various former officers and employees of KCI" and Dr. Paul Svedman, who is a Swedish physician. *Id.* at ¶ 15. ITI alleges that it intends to compete with KCI in the area of negative pressure wound therapy systems through a new device called the "Svedman Wound Treatment System" ("Svedman System"). Complaint ¶¶ 15-16. The complaint states that "ITI intends to begin offering the Svedman [System] to certain potential customers on or about October 1, 2007." *Id.* at ¶ 17. ITI is seeking a declaration from this Court that five patents in this field are either invalid or not infringed. *Id.* at Counts 1-10.

As described in the Preliminary Statement, *supra*, prior to the filing of the complaint, former KCI employee David Tumey (who was KCI's Director of Research and Development, but is now an officer with ITI) telephoned two of his former colleagues at KCI (Michael Burke and Michael Girouard) in an apparent attempt to get them to say something that would provide a jurisdictional basis for ITI's complaint. However, neither Mr. Burke nor Mr. Girouard had ever seen ITI's claimed product, the Svedman System, and to KCI's knowledge, no one else associated with KCI (including its counsel) has seen it to this day. Declaration of Michael Burke ("Burke Decl.") at ¶ 8; Declaration of Michael Girouard ("Girouard Decl.") at ¶ 11; Declaration of Don Burley ("Burley Decl.") at ¶ 4. Indeed, although KCI's counsel asked to inspect and photograph the Svedman System, ITI's counsel refused that request as well as a request to

provide KCI's counsel with literature concerning the Svedman System, and also indicated that no Svedman System had been sold as of October 9, 2007. Burley Decl. at ¶ 6.¹

B. ITI's Allegations That There Is a Dispute Between ITI and KCI

ITI's allegation that "an actual and substantial controversy now exists between ITI and [KCI]" (Complaint at ¶ 21) has three bases: (i) the statements the two KCI employees made to Mr. Tumey (*id.* at ¶ 20); (ii) KCI's lawsuits against *other* parties (*id.* at ¶ 18); and (iii) a statement KCI made in an SEC Form 10-K regarding its intellectual property (*id.* at ¶ 19).

1. KCI's Alleged Threats of Litigation Against ITI

The only claims that ITI makes of an alleged dispute specifically between it and KCI are found in paragraph 20 of ITI's complaint. ITI states that "[t]he KCI defendants are aware that ITI has received FDA approval for a negative pressure wound therapy device, and they have expressly warned ITI of the likelihood that they will sue ITI for patent infringement." Complaint at ¶ 20. As support for this statement, ITI cites two conversations that "an ITI officer" and "ITI representatives" had with KCI employees. *Id.*

The first of these conversations is described as between an "an ITI officer" and KCI's "Senior Vice President of Manufacturing and Executive Committee Member Mike Burke." *Id.* According to the complaint, Mr. Burke said "that the odds are '100%' that KCI will sue ITI if it launches a negative pressure, foam-based wound treatment device." *Id.* The second

¹ While the complaint also alleges that KCI knew that ITI had "received FDA approval for a negative pressure wound therapy device" (Complaint at ¶ 20), it turns out that ITI has obtained FDA approval for two devices (called the ANTLIA I and the ANTLIA II), and the complaint fails even to indicate which of these two devices is the Svedman System (assuming that one is). Further, when KCI's counsel put this question to ITI's counsel, ITI's counsel said that it was his understanding of the law that ITI could "mix and match" between the two FDA approvals and that he did not know that you could say that the Svedman Device is limited to one or the other (i.e., the ANTLIA I or the ANTLIA II). Burley Decl. at ¶ 6.

conversation is described as between “ITI representatives” and KCI’s “Director of Marketing,” Michael Girouard, who, according to the complaint, said that *if* KCI believes that the ITI product infringes any of KCI’s patents, “KCI will respond aggressively.” *Id.*

The complaint hardly tells the complete story of the two conversations, however. It turns out that both conversations were initiated by former KCI employee David Tumey, and that he called both Mr. Burke and Mr. Girouard under the pretext of friendship.² Further, Mr. Tumey said nothing to either person about the fact that ITI was intending to sue KCI and that his real purpose in calling was to fish for a sound-bite that would create a jurisdictional basis for ITI’s suit.

For example, Mr. Tumey began his conversation with Mr. Burke, his former supervisor at KCI, by telling him that he was calling to congratulate Mr. Burke on his upcoming retirement. Then, after talking about what Mr. Burke might do during his retirement, Mr. Tumey asked Mr. Burke for some “fatherly advice.” Burke Decl. at ¶ 7. Similarly, Mr. Tumey attempted to reach Mr. Girouard by calling him at home. After Mr. Girouard did not return Mr. Tumey’s call to his home, Mr. Tumey left a message with Mr. Girouard’s assistant at work, saying that “friends call friends back.” Girouard Decl. at ¶ 6.

During each conversation, it was Mr. Tumey who broached the topic of KCI’s patent portfolio and Mr. Tumey’s intention to sell a product that would compete with KCI’s patented V.A.C.® technology, which is a negative pressure wound treatment system. Burke Decl. at ¶ 7; Girouard Decl. at ¶¶ 8-10. Before Mr. Tumey called them, neither Mr. Burke nor Mr. Girouard

² During the same general time that he spoke with Mr. Burke and Mr. Girouard, Mr. Tumey also tried, unsuccessfully, to initiate numerous other conversations with his former colleagues at KCI. *See* Declaration of Lynne Sly (“Sly Decl.”) at ¶ 4; Declaration of Jon Jaeb, Sr. (“Jaeb Decl.”) at ¶ 4.

knew anything about ITI, or Mr. Tumey's involvement with the company, or was even aware of the product Mr. Tumey wanted to discuss. Burke Decl. at ¶ 11; Girouard Decl. at ¶ 11.

Moreover, both Mr. Burke and Mr. Girouard told Mr. Tumey that they *did not know* what KCI would do if Mr. Tumey were to launch his product. Burke Decl. at ¶ 8; Girouard Decl. at ¶ 10. And they also made clear to Mr. Tumey that they were not the appropriate people at KCI to discuss this matter (a fact Mr. Tumey undoubtedly already knew). Burke Decl. at ¶¶ 3, 7-8; Girouard Decl. at ¶¶ 3, 10.³

Mr. Burke recalls telling Mr. Tumey something to the effect that if KCI believed that someone violated its patents, he assumed KCI would take action, but he also recalls telling Mr. Tumey, repeatedly, that he was “not in the loop” and in no position to speak for KCI on legal matters. Burke Decl. at ¶¶ 7-8. Further, Mr. Burke’s recollection of his conversation with Mr. Tumey is inconsistent with ITI’s characterization of it. Specifically, while the complaint alleges that Mr. Burke said he was “100%” certain that KCI would sue ITI, Mr. Burke recalls that it was Mr. Tumey who said “100%” in the context of a question that he responded to by repeating that he was out of the loop and did not know what KCI would do. *Id.* at ¶ 9.

Similarly, Mr. Girouard remembers telling Mr. Tumey that KCI would look at the product, and *if* it concluded that it infringed a KCI patent, KCI would probably take legal action. But he also remembers telling Mr. Tumey that he did not know whether KCI would take any action regarding his product, that this would not be his determination in any event, and also that Mr. Tumey was more knowledgeable about KCI’s patents than he was. Girouard Decl. at ¶ 10.

³ Mr. Tumey’s failed attempts to discuss his intentions with other KCI employees were also with people who had no role in deciding whether or not KCI would sue an infringer. Sly Decl. at ¶ 2; Jaeb Decl. at ¶ 2.

In short, it is clear that both Mr. Burke and Mr. Girouard were providing only their personal opinions of what KCI might do in a given hypothetical situation and not speaking for KCI regarding what it would do in response to the launch of the Svedman System, and that the only reason they even offered their speculation was that they were urged to do so by Mr. Tumey.

2. KCI's Lawsuits Against *Other* Parties

ITI alleges that its position that there is a dispute between it and KCI is also supported by the fact that KCI has asserted its patents against *other* parties in the past. Complaint at ¶ 18. Specifically, ITI alleges that “KCI, Inc. has sued no fewer than ten different defendants in the past six years for alleged infringement of the patents in suit.” *Id.*

In reality, however, ITI has exaggerated the number of disputes in which KCI has been involved, and ITI ignores the fact that KCI’s product has been on the market since 1995 and that we are thus dealing with a 12-year period. In particular, four of the six cases cited in support of ITI’s statement involve just two groups of related companies (BlueSky Medical, Medela, and their parent and sibling companies). *Id.*

3. KCI’s Statement in Its SEC Form 10-K That Its Intellectual Property Is Important

ITI also alleges that an actual dispute exists between it and KCI based on KCI’s statement in an SEC Form 10-K that “[i]f we are unsuccessful in protecting and maintaining our intellectual property, particularly our rights under the Wake Forest patents, our competitive position would be harmed.” Complaint at ¶ 19. However, this generalized statement—which appears in a section of the Form 10-K discussing “risk factors” that is required by 17 C.F.R. § 229.503(c)—mentions neither ITI nor any other particular competitor. In fact, the only companies mentioned in the context of KCI’s patents are BlueSky and Medela, companies that were already involved in litigation against KCI. *See* Burley Decl. at ¶ 8 and Ex. 3.

III. ARGUMENT

A. Declaratory-Judgment Jurisdiction Requires a Definite and Concrete Dispute Between the Parties

For there to be jurisdiction in a declaratory-judgment action, there must be an “actual case or controversy” that is justiciable under Article III. *See* 21 U.S.C. § 2201; *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 778 (2007). Further, “[t]he declaratory judgment plaintiff carries the burden of proving ‘the existence of facts underlying’ his allegations of the existence of an actual controversy.” *Indium Corp. v. Semi-Alloys, Inc.*, 781 F.2d 879, 883 (Fed. Cir. 1985) (citation omitted).

Prior to the Supreme Court’s *MedImmune* decision, the Federal Circuit applied a two-part test to determine whether there was an actual case or controversy in suits requesting a declaration of patent noninfringement, invalidity, or unenforceability. As the Federal Circuit explained in *Sony Electronics, Inc. v. Guardian Media Technologies, Ltd.*, 497 F.3d 1271, 1283 (Fed. Cir. 2007), “[o]ne prong of the test examined whether the declaratory judgment plaintiff actually produced or was prepared to produce an allegedly infringing product. The other prong looked to see whether conduct by the patentee had created on the part of the declaratory judgment plaintiff a reasonable apprehension that the patentee would file suit if the allegedly infringing activity continued.” The Supreme Court’s decision in *MedImmune*, however, abrogated the “reasonable apprehension of suit” test. *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007).

While *MedImmune* rejected the Federal Circuit’s “reasonable apprehension of suit” test, it also made clear that the boundaries of what constitutes an appropriate declaratory-judgment action are not limitless. In discussing what a declaratory-judgment plaintiff must show to establish jurisdiction, the Court said that its “decisions have required that the dispute be ‘definite

and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character.''" 127 S. Ct. at 771. Further, the Court added that there must be "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* In contrast, declaratory relief is not available where a party is seeking "an opinion advising what the law would be upon a hypothetical state of facts." *Id.* at 771 (citation omitted). As the Federal Circuit said in *Shell Oil Co., v. Amoco Corp.*, 970 F.2d 885, 889 (Fed. Cir. 1992), "[t]he Declaratory Judgment Act was intended to protect threatened parties, not to drag a non-threatening patentee into court."

B. There Was No Dispute Between ITI and KCI at the Time ITI Filed Its Complaint

1. The Personal Opinions of Two KCI Employees Not Involved in Decision-Making, Which Were Equivocal in Any Event, Do Not Establish the Existence of a Definite and Concrete Dispute

There was no definite and concrete dispute between KCI and ITI at the time ITI filed its complaint. ITI's complaint rests primarily on the two telephone conversations between Mr. Tumey and KCI's Mr. Burke and Mr. Girouard. As is apparent from their declarations, however, ITI's complaint tells an incomplete story at best. In each case, Mr. Tumey understood—*because he was told*—that neither Mr. Burke nor Mr. Girouard was speaking on behalf of KCI or could state what KCI might do if ITI were to launch a product that KCI had not yet even seen.

In an effort to manufacture the dispute described in ITI's complaint, ex-KCI employee Mr. Tumey reached out to former co-workers under the guise of friendship, telling Mr. Burke, for example, that he was calling him to congratulate him on his retirement. *See supra* page 4. Similarly, Mr. Tumey played off his personal relationship with Mr. Girouard, imploring him to return his call because "friends call friends back." *See id.*

Having reached out to both Mr. Burke and Mr. Girouard in this way, Mr. Tumey then set out to elicit sound bites from them that ITI could use in its complaint. In telling Mr. Burke that he was seeking “fatherly advice” from him, however, Mr. Tumey misled Mr. Burke. Similarly, Mr. Tumey took unfair advantage of his past relationship with Mr. Girouard when he entreated Mr. Girouard to return his call because “friends call friends back.”

Moreover, irrespective of the methods by which Mr. Tumey got Mr. Burke and Mr. Girouard to talk to him, ITI’s complaint fails to tell the complete story. It ignores the equivocations of both men, including Mr. Burke’s repeated statements that he was out of the loop and could not speak for KCI on legal matters, as well as Mr. Girouard’s statements that he did not know whether KCI would take any action regarding his product, that this would not be his determination in any event, and also that Mr. Tumey knew more about KCI’s patents than he did. *See supra* page 5.

In short, there can be no question that the statements ITI quotes in its complaint are *not* the positions of KCI. Even if one *completely* accepts ITI’s version of events, what Mr. Burke and Mr. Girouard said are only the personal opinions of two KCI employees and thus wholly inadequate to establish the existence of a definite and concrete dispute between KCI and ITI. *See, e.g., Boler Co. v. Raydan Mfg., Inc.*, 415 F. Supp. 2d 896, 902 (N.D. Ill. 2006) (stating that courts “consistently have held that unless an agent has actual or apparent authority to assert claims of patent infringement or to initiate suit on the patentee’s behalf, the agent’s statements are insufficient to create an actual controversy”). Further, this conclusion would not change even if Mr. Burke’s and Mr. Girouard’s statements could be fully attributed to KCI. Taken as a whole, both persons’ statements are entirely equivocal, reflecting the fact that neither person had seen the Svedman System or knew anything about either the Svedman System or ITI.

2. The Existence of a Dispute Between ITI and KCI Is Not Shown By Either KCI's Suits Against Other Parties or KCI's General Statements About the Importance of Its Intellectual Property

The only other allegations in ITI's complaint concerning a dispute between it and KCI relate to KCI's past litigation behavior and an SEC Form 10-K in which KCI stated (in a required section discussing "risk factors") that it considers its intellectual property an important part of its business. Neither provides any basis for finding declaratory-judgment jurisdiction in this case.

ITI's characterization of KCI as an aggressive litigant (*see supra* page 6) is hyperbole. Contrary to ITI's characterization, KCI has been involved in just a handful of disputes in the twelve years it has been in the market. *Id.*

More importantly, as both a logical and a legal matter, KCI's prior suits against unrelated third parties do not establish a dispute between KCI and ITI. Apparently, ITI mentions KCI's past litigations in an attempt to portray KCI as a historically aggressive litigant, which would provide some basis for ITI to fear that it could be next in line if it launched the Svedman Device. But even if ITI's *apprehension* of suit (whether reasonable or not) has any relevance at all after *MedImmune* (*see supra* pages 7-8), it is noteworthy that pre-*MedImmune* cases gave little weight to a patentee's past litigation behavior in considering whether declaratory-judgment jurisdiction existed. *See, e.g., West Interactive Corp. v. First Data Resources*, 972 F.2d 1295, 1298 (Fed. Cir. 1992) (stating that "First Data's litigation against unrelated third parties did not give West an objective reason to fear litigation"). Indeed, the Seventh Circuit (in a case decided before the Federal Circuit was founded), determined that even a prior litigation between the patentee and the declaratory-judgment plaintiff "cannot be viewed as anything more than a general indication that [the patentee] considers litigation a viable alternative once it has determined that a

competitor is producing a product which infringes the patent at issue here.” *Int’l Harvester Co. v. Deere & Co.*, 623 F.2d 1207, 1212 (7th Cir. 1980).

The same is true for KCI’s statement to the SEC. *See supra* page 6. A company saying that failing to protect its intellectual property would harm its competitive position amounts to no more than a truism, and hardly establishes a definite and concrete dispute between the company and all of its existing or possible competitors. Even under the now-defunct “reasonable apprehension of suit” test, statements of this kind were not considered adequately threatening to justify a declaratory-judgment action:

A generalized statement to the public that one will protect its rights can hardly generate much surprise or alarm. It cannot reasonably create the same sense of apprehension as a statement directed to a particular party that is made immediately after the speaker has accused the other party with infringement.

Eloica, S.A. v. General Elec. Co., No. 04-C-43-C, 2004 WL 1196870, at *5 (W.D. Wis. May 18, 2004).

In sum, there is no definite and concrete dispute between ITI and KCI. Mr. Tumey’s phone conversations with Mr. Burke and Mr. Girouard are insufficient to establish a dispute. Similarly, the existence of a dispute between ITI and KCI is not shown either by KCI’s suits against *other* parties or by KCI’s statement to the SEC in its Form 10-K that failing to protect its intellectual property would hurt it competitively. Accordingly, there is no jurisdiction over ITI’s complaint and it should be dismissed.⁴

⁴ There is also a question in this case regarding whether any dispute that might exist between ITI and KCI is of sufficient “immediacy and reality” to demonstrate declaratory judgment jurisdiction. Despite the allegation in ITI’s complaint that it intended to begin offering the Svedman System “to certain potential customers on or about October 1, 2007” (Complaint at ¶ 17), there is no evidence that this has actually occurred. As noted above, in fact, ITI’s counsel told KCI’s counsel on October 9, 2007, that no Svedman System had been sold as of that date. Burley Decl. at ¶ 6. The requirement that the dispute between the parties be of sufficient (continued...)

C. Even if This Court Were to Find Jurisdiction, the Court Should Exercise Its Discretion and Decline to Hear the Case

Even if the Court were to conclude that ITI's allegations are sufficient to meet the "actual controversy" requirement for declaratory-judgment jurisdiction, the Court should exercise its discretion to decline to hear ITI's case. In *MedImmune*, the Supreme Court said that the Declaratory Judgment Act gives district courts a "unique and substantial discretion in deciding whether to declare the rights of the litigants." 127 S. Ct. at 776 (quoting *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995)). Similarly, this has been the long-stated position of the Federal Circuit. In *EMC Corp. v. Norand Corp.*, 89 F.3d 807 (Fed. Cir. 1996), for example, the Federal Circuit said that even if the "actual controversy" requirement for declaratory-judgment jurisdiction is met, that "does not mean that the district court is required to exercise that jurisdiction." *Id.* at 813. Rather, the Court need only "act[] in accordance with the purposes of the Declaratory Judgment Act and the principles of sound judicial administration" in reaching its decision. *Id.* at 813-14.

Further, it has been found that where the declaratory-judgment plaintiff has engaged in gamesmanship, jurisdiction should be declined as inconsistent with the purposes of the Declaratory Judgment Act. In *EMC*, for example, the Federal Circuit affirmed the district court's decision to decline to entertain a declaratory-judgment action of invalidity and noninfringement where it concluded that the declaratory-judgment plaintiff had filed suit during

(...continued)

"immediacy and reality" was recently addressed in *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007). There, although Benitec had already sued Nucleonics for infringement (but dismissed that suit), the Federal Circuit held that Nucleonics' stated intention to expand its activities into other related areas did not provide declaratory judgment jurisdiction. *Id.* at 1348-49 (stating that Nucleonics "failed to show that its future plans meet the immediacy and reality requirement of *MedImmune* necessary to support a justiciable controversy").

licensing negotiations as a tactical measure to improve its negotiation position. As the Federal Circuit found, filing suit to gain a tactical advantage in this way is “not a purpose the Declaratory Judgment Act was designed to serve.” *Id.* at 815. *See also Serco Servs. Co. v. Kelley Co.*, 51 F.3d 1037, 1039-40 (Fed. Cir. 1995) (finding no abuse of discretion when district court declined to hear first-filed declaratory-judgment action in favor of patentee’s infringement suit filed three days later, where court found that declaratory-judgment action was “intended to preempt” patentee’s suit and conveniences of witnesses and location of evidence favored second-filed forum).

Similarly, even if jurisdiction were found to exist here, exercising it would be inconsistent with the purposes of the Declaratory Judgment Act. Mr. Tumey (acting on behalf of ITI) misled Mr. Burke and Mr. Girouard into thinking that he was calling them as friends. In reality, the sole purpose of Mr. Tumey’s phone calls was to manufacture a dispute where none existed in an attempt to gain the tactical advantage of litigating in the forum of ITI’s choice. This is precisely the type of litigation tactic that the Federal Circuit said in *EMC* was inconsistent with the purposes of the Declaratory Judgment Act. For this reason, the Court should decline to hear ITI’s case even if jurisdiction exists.

IV. CONCLUSION

For the foregoing reasons, the Court should grant KCI's motion and dismiss ITI's complaint for lack of subject matter jurisdiction. Alternatively, if jurisdiction exists, the Court should decline to exercise it.

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Tiffany Geyer Lydon (I.D. #3950)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
302-654-1888

Of Counsel:

Don O. Burley
FINNEGAN, HENDERSON, FARABOW, *Attorneys for Defendants*
GARRETT & DUNNER, L.L.P.
901 New York Avenue, NW
Washington, DC 20001
202-408-4000

Erik R. Puknys
Jason M. Webster
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
3300 Hillview Avenue
Palo Alto, CA 94304
650-849-6600

R. Laurence Macon
AKIN GUMP STRAUSS HAUER
& FELD LLP
300 Convent Street, Suite 1500
San Antonio, TX 78205
210-281-7000

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